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Patent Application

Inventors(s):	Susanne Arney Timofei Nikita Kroupenkine Donald Weiss	**Case:**	10-18-4
Serial No.:	10/798,064	**Filing Date:**	March 11, 2004
Examiner:	Brian E. Pellegrino	**Group Art Unit:**	3738
Title:	Drug Delivery Stent		

THE COMMISSIONER OF PATENTS AND TRADEMARKS
ALEXANDRIA, VA 22313-1450

SIR:

DECLARATION OF DR. THOMAS NIKITA KRUPENKIN
UNDER 37 C.F.R. § 1.132

1) I, Thomas Nikita Krupenkin (*aka* Timofei Nikita Kroupenkine), received a Ph.D. in Physics from the Case Western Reserve University in 1996. From 1998 to 2007, I was a Member of the Technical Staff at Bell Laboratories. Presently, I am a Professor with the Department of Mechanical Engineering at the University of Wisconsin-Madison.

2) My scientific research has involved primarily the interaction of solid surfaces and liquids, including the electro-wetting of nanostructured solid surfaces. The device applications of my research include, for example, optical waveguides actuated by electro-wetting, dynamically controllable biological/chemical detectors having nanostructured surfaces, electro-wetting batteries having nanostructured electrode surfaces, drug delivery stents having nanostructured surfaces for controlling

hydrophobicity, and tunable liquid microlenses. I am an author or co-author of at least 30 scientific articles and have been a contributor to scientific presentations at at least 50 scientific conventions. In addition, I am the inventor or co-inventor of at least 33 US pending patent applications and 20 issued US patents.

3) I am a co-inventor on the above-captioned patent application.

4) In preparation for this Declaration, I reviewed the above- captioned application as well as an article entitled "Wetting," which is of record in the above- captioned application and is currently available on the internet at the ***Wikipedia*** website at http://en.wikipedia.org/wiki/Wetting (hereinafter ***Wikipedia***).

5) Based on my scientific experience and education, as well as the reviews identified above, I have the following understanding of the term ***hydrophobicity***. The standard, well-known definition of ***hydrophobicity*** is correctly set forth in the above article from ***Wikipedia.*** The article begins by describing the phenomenon of ***wetting*** as the "contact between a liquid and a solid surface." From the standpoint of fundamental surface physics, the article also states correctly that the "degree of wetting is described by the contact angle" and that a "contact angle of 90° or greater generally characterizes a surface as not-wettable, and one less than 90° as wettable. In the context of water, the article states that "a wettable surface may also be termed ***hydrophilic*** and a not-wettable surface ***hydrophobic***." This statement is correct for aqueous liquids in general. Thus, the article clearly and correctly teaches that a hydrophobic surface is not wettable and, therefore, has a contact angle greater than 90° to a water droplet (Figure 1). Applicants' use of the term follows this standard definition; that is, Applicants' specification (page 5, line 21) explicitly states that a hydrophobic surface is "a low-energy surface that is characterized by a high contact angle (> 90°) to any body fluid it contacts." (This limitation is explicit in independent claims 1 and 18.) Since it is notoriously well known that body fluids, such as blood, are aqueous, it follows that the standard definition of ***hydrophobic*** is equally applicable to Applicants' invention

and is essentially identical with the explicit definition given in Applicants' specification.

6) In preparation for this Declaration, I have also reviewed the following statement made by the Examiner at page 2 (and elsewhere) of the Final Rejection of May 9, 2008: "Please note that the Examiner is interpreting hydrophobic according to a known, common definition. ***According to Dorland's Illustrated Medical Dictionary* (2003) *hydrophobic is defined as: not readily absorbing water*.** Thus, since it is known metals do not absorb water, the surface of [the prior art stent] must be hydrophobic. The surface is fully capable of having hydrophobicity that has a contact angle greater than 90° when a drop of fluid contacts it." This dictionary will hereinafter be referred to as ***Dorland***.

7) Based on my scientific experience and education, as well as the reviews identified above, I conclude that ***Dorland's*** definition describes a ***necessary but not sufficient*** condition that is inherent in any hydrophobic surface; that is, the surface does not absorb water. But, the ***Dorland*** definition is incomplete because it fails to consider the critical nature of ***adsorption***, particularly in the interaction between water and a hydrophobic surface. In standard surface physics that interaction is defined in terms of the contact angle between the hydrophobic surface and a water droplet (cf., Figure 1, ***Wikipedia***). The missing aspects of the ***Dorland*** definition are particularly important because Applicants' invention is predicated on the use of a nanostructured surface to dynamically control the hydrophobicity of that surface. In one important embodiment of Applicants' invention, this dynamic control involves the application of suitable voltages to the stent, which allows a pharmacological agent or a drug to be alternately captured by or released by the nanostructured stent surface.

8) At page 8 of his Response to Arguments (Final Office action above) the Examiner asserts, without support, that Applicants have adopted a "special definition" of hydrophobic. In addition, the Examiner also asserts that "the limitation of 'a

PAGE 26/28 * RCVD AT 7/29/2008 2:56:56 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-6/29 * DNIS:2738300 * CSID:Michael J. Urbano * DURATION (mm-ss):04-44

contact angle greater than 90° when a fluid contacts the surface' is a description of the characteristics of a treated surface, it is not the definition of 'hydrophobic." To the contrary, as paragraphs (4-7) above demonstrate, Applicants' definition of hydrophobic is the ***standard*** definition well known in the physics art used to analyze the interaction between liquids and the surface of a solid. This definition, soundly based in surface physics, is applicable to the art of Applicants' invention. In contrast, ***Dorland's*** definition is incomplete.

9) Based on my scientific experience and education, as well as the reviews identified above, I further conclude that the Examiner's position on metals is also fallacious; that is, the Examiner asserts that metals don't absorb; therefore, metals must be hydrophobic. This argument contravenes the standard definition of hydrophobicity, as discussed above. Second, the prior art teaches that the contact angles of illustrative clean metal surfaces are ***hydrophilic, not hydrophobic***; that is, they have contact angles less than 90° (Au ~ 71°; Pt ~ 0°; stainless steel < 5°). Thus, the Examiner's ***unsupported assumption*** is without foundation in the art. Moreover, the further assumption that "[any metal] surface is ***fully capable*** of having a hydrophobicity that has a contact angle greater than 90°" is not supported by the prior art.

10) At page 8 of his Response to Arguments (Final Office action above) the Examiner asserts that Applicants' definition of hydrophobic "is describing a characteristic of the surface as a result of Applicants' ***process of treating the surface with a voltage***."

11) Based on my scientific experience and education, as well as the reviews identified above, I further conclude that the Examiner's assertion in paragraph (10) above, is incorrect in two respects. First, Applicants' definition does not describe a "process of treating" a surface; rather, it describes that nature of a surface in contact with an aqueous liquid. Thus, the Examiner is correct that Applicants' definition of hydrophobic describes a characteristic of a [nanostructured] surface,

but that surface is hydrophobic ***without*** the application of voltage. The role of voltage is, in one embodiment of Applicants' invention, the dynamic control of hydrophobicity. For example, application of a suitable voltage to Applicants' stent allows the hydrophobicity (contact angle) to be lowered, which in turn permits a fluid suspended across the pillars of a nanostructured surface to penetrate the interstices (i.e., the stent is loaded with a pharmaceutical agent or drug) or conversely (i.e., the agent or drug is released by the stent into a body fluid).

12) I herein certify that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true. I also understand that willful false statements and the like are punishable by fine, imprisonment or both under 18 U.S.C. 1001 and that willful false statements and the like may jeopardize the validity of the application-at-issue or any patent issuing thereon.

Thomas Nikita Krupenkin, Ph.D.

Executed on 07/29/08
Date